



**GENTECH HEALTHCARE PVT. LTD.**  
1470, HSIIDC, Rai- 131029, (INDIA)

**CERTIFICATE OF ANALYSIS  
FINISHED PRODUCT**

Brand Name	TOFAMET - 5	Generic Name	Tofacitinib Citrate 5 mg
Batch No.	GENT6013A	Batch No.	GENT6013
Packed Size:	0.30 lac. Tablets	Batch Size:	0.90 lac. Tablets
Mfg. Date:	04/2023	Date of Sampling:	24/04/2023
Exp. Date:	03/2025	Date of Release:	24/04/2023
Specification No.:	SFS/924-00	A.R.Number:	FPGENT23224
STP No. :	STP/924-00	Reference:	IHS

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	White colour circular shaped biconvex both side plain film coated tablets.	White colour circular shaped biconvex both side plain film coated tablets.
2.	Identification	The retention time of major peak in the chromatogram of the assay preparation correspond to that in the chromatogram of the standard preparation as obtained in the assay.	Complies
3	Average Weight of Tablet	153 mg $\pm$ 7.5 % (141.52 mg to 164.47mg)	154.37 mg

Remarks : In the opinion of the undersigned the sample complies / does not comply with the IP/BP/USP/In-House Specifications.

	Prepared By	Checked By	Approved By
Department	Executive QC/designee	Astt. Manager QC/designee	Manager QC
Name	Krishna Biya Sikarwar	Sumit Jain	Santosh Singh
Date	24/04/2023	24/04/2023	24/04/2023
Signature			



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4.	Uniformity of dosage Units (By Weight Variation)	Complies as per IP	Complies
5.	Disintegration	NMT 30 min	5 min 16 sec
6.	Assay Each film coated tablet contains. Tofacitinib Citrate Eq. to Tofacitinib 5 mg	Limit	Result
		4.5 mg to 5.5 mg (90 % to 110%)	4.953 mg (99.06 %)

**Remarks :** In the opinion of the undersigned the sample complies / does not comply with the IP/BP/USP/In-House Specifications.

	Prepared By	Checked By	Approved By
Department	Executive QC/designee	Astt. Manager QC/designee	Manager QC
Name	Krishna Priya Sikarwar	Sumit Saini	Santosh Singh
Date	24/04/2023	24/04/2023	24/04/2023
Signature	KPS	[Signature]	[Signature]